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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,980	09/10/2002	Vicente Javier Benedi Benito	84086	5781

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER

STRZELECKA, TERESA E

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/009,980	Applicant(s) BENEDI BENITO ET AL.	
	Examiner Teresa E Strzelecka	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-26 is/are pending in the application.
- 4a) Of the above claim(s) 8-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-25 is/are rejected.
- 7) ☒ Claim(s) 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/2/2002</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group III (claims 18-26) in the reply filed on December 6, 2004 is acknowledged.
2. Claims 8-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on December 6, 2004.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Priority

4. Acknowledgment is made of applicant's claim for foreign priority based on an application P200000560 filed in Spain on March 8, 2000. It is noted, however, that applicant has not filed a certified copy of the P200000560 application as required by 35 U.S.C. 119(b).

Therefore, the priority date of the instant claims is March 2, 2001.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on February 22, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Interpretation

6. The preamble to claim 18, "A method for obtaining extracted DNA from gum samples comprising one or more of guar gum (E412) and locust bean gum (E410)" is interpreted as a method to obtain any DNA from any sample which contains one or both gums.
7. The term "decantation" is interpreted as removal of liquid by pouring it or siphoning it off from a container.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 18, 19, 21-23 and 25 are rejected under 35 U.S.C. 102(a) as being anticipated by Meyer et al. (J. AOAC Int., vol. 84, pp. 89-99, January 2001).

Regarding claim 18, Meyer et al. teach a method of extracting DNA from samples containing guar gum and locust bean gum (Abstract), the method comprising:

- i) contacting a gum sample comprising DNA and one or more of guar gum (E412) and locust bean gum (E 410) with an aqueous solution to form an extraction mixture (Meyer et al. teach contacting a sample containing guar gum, locust bean gum or both (Table 2, page 92) with an aqueous solution to form an extraction mixture (page 90, last paragraph; page 92, first paragraph).);
- ii) agitating the extraction mixture at a temperature between 0°C and 100°C for a time period sufficient to permit extraction of DNA from the gum sample into the aqueous solution (Meyer et al.

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teach vortexing (= agitating) the extraction mixture (page 92, first paragraph). Meyer et al. do not specifically teach a temperature between 0°C and 100°C, but since the temperature is not specified, it was inherently room temperature, which is usually between 15 and 25°C, therefore, between 0°C and 100°C.);

iii) separating the extraction mixture to obtain an aqueous solution containing extracted DNA and another phase (Meyer et al. teach separating the extraction mixture by addition of chloroform and centrifugation, to obtain extracted DNA in the supernatant and chloroform phase (page 92, first paragraph).); and

iv) recovering a sample of the aqueous solution containing extracted DNA (Meyer et al. teach recovering the extracted DNA by passing the supernatant through a QIAamp Maxi column (page 92, first paragraph).).

Regarding claim 19, Meyer et al. teach buffered aqueous solution (page 90, last paragraph; page 92, first paragraph).

Regarding claim 21, Meyer et al. teach vortexing (= agitating) the extraction mixture (page 92, first paragraph). Meyer et al. do not specifically teach room temperature, but since the temperature is not specified, it was inherently room temperature.

Regarding claim 22, Meyer et al. teach transferring of the supernatant from the tube after chloroform extraction (page 92, first paragraph), therefore they teach separation of the extraction mixture by decantation.

Regarding claim 23, Meyer et al. teach separating the extraction mixture by centrifugation (page 92, first paragraph).

Regarding claim 25, Meyer et al. teach amplifying the extracted DNA by PCR (page 93, third and fourth paragraphs; Fig. 2, 3).

10. Claims 18, 19, 21-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (J. AOAC Int., vol. 78, pp. 1542-1551, 1995), as evidenced by Meer (Food Colloids, Graham, H.D. editor, The AVI Publishing Company, Inc., Westport, Connecticut, pp. 522-539, 1977).

Regarding claim 18, Meyer et al. teach a method of extracting DNA from processed meat samples (Abstract), the method comprising:

i) contacting a gum sample comprising DNA and one or more of guar gum (E412) and locust bean gum (E 410) with an aqueous solution to form an extraction mixture (Meyer et al. teach contacting a processed meat sample (Table 2, page 1544) with an extraction buffer (= an aqueous solution) to form an extraction mixture (page 1544, second paragraph). Meyer et al. do not specifically teach samples containing guar gum or locust bean gum. As evidenced by Meer, locust bean gum is used as a stabilizer in processed meats, salami, bologna and pork sausages (page 534, fifth paragraph). Therefore, by teaching samples of salami and pork sausages, Meyer et al. inherently teach samples containing locust bean gum.);

ii) agitating the extraction mixture at a temperature between 0°C and 100°C for a time period sufficient to permit extraction of DNA from the gum sample into the aqueous solution (Meyer et al. teach mixing the extraction mixture by inversion (= agitating) (page 1544, second paragraph). Meyer et al. do not specifically teach a temperature between 0°C and 100°C, but since the temperature is not specified, it was inherently room temperature, which is usually between 15 and 25°C, therefore, between 0°C and 100°C.);

iii) separating the extraction mixture to obtain an aqueous solution containing extracted DNA and another phase (Meyer et al. teach separating the extraction mixture by centrifugation, to obtain extracted DNA in the supernatant and a pellet (page 1544, second paragraph).); and

iv) recovering a sample of the aqueous solution containing extracted DNA (Meyer et al. teach recovering the extracted DNA by adding to the supernatant Wizard DNA purification resin and eluting purified DNA (page 1544, second paragraph).).

Regarding claim 19, Meyer et al. teach buffered aqueous solution (page 1544, second paragraph).

Regarding claim 21, Meyer et al. teach mixing the extraction mixture by inversion (page 1544, second paragraph). Meyer et al. do not specifically teach room temperature, but since the temperature is not specified, it was inherently room temperature.

Regarding claim 22, Meyer et al. teach transferring of the supernatant from the tube after centrifugation (page 1544, second paragraph), therefore they teach separation of the extraction mixture by decantation.

Regarding claim 23, Meyer et al. teach separating the extraction mixture by centrifugation (page 1544, second paragraph).

Regarding claim 25, Meyer et al. teach amplifying the extracted DNA by PCR (page 1544, fourth paragraph; Fig. 1).

11. Claims 18, 19, 20-23 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Drake et al. (J. Food Protect., vol. 59, pp. 1031-1036, 1996), as evidenced by Meer (Food Colloids, Graham, H.D. editor, The AVI Publishing Company, Inc., Westport, Connecticut, pp. 522-539, 1977).

Regarding claim 18, Drake et al. teach a method of extracting DNA from processed meat samples (Abstract), the method comprising:

i) contacting a gum sample comprising DNA and one or more of guar gum (E412) and locust bean gum (E 410) with an aqueous solution to form an extraction mixture (Drake et al. teach

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contacting cheese and yoghurt samples (page 1033, third paragraph) with an extraction buffer (= an aqueous solution) to form an extraction mixture (page 1033, fourth paragraph). Drake et al. do not specifically teach samples containing guar gum or locust bean gum. As evidenced by Meer, guar gum and locust bean gum are used in cheeses (page 533, first paragraph; page 534, last paragraph, page 535, first paragraph). Therefore, by teaching samples of cheeses, Drake et al. inherently teach samples containing guar gum and/or locust bean gum.);

ii) agitating the extraction mixture at a temperature between 0°C and 100°C for a time period sufficient to permit extraction of DNA from the gum sample into the aqueous solution (Drake et al. teach mixing the extraction mixture by repeated pipetting (= agitating) (page 1033, fourth paragraph). Drake et al. do not specifically teach a temperature between 0°C and 100°C, but since the temperature is not specified, it was inherently room temperature, which is usually between 15 and 25°C, therefore, between 0°C and 100°C.);

iii) separating the extraction mixture to obtain an aqueous solution containing extracted DNA and another phase (Drake et al. teach separating the extraction mixture by centrifugation, followed by phenol and phenol: chloroform extraction, to obtain extracted DNA in the supernatant and another phase, containing proteins and other molecules (page 1033, fourth paragraph).); and

iv) recovering a sample of the aqueous solution containing extracted DNA (Drake et al. teach recovering the extracted DNA by precipitation of DNA with 3 M sodium acetate, centrifugation, and resuspension of the pellet in sterile water (page 1033, fourth paragraph).).

Regarding claim 19, Drake et al. teach aqueous solution containing 2% sodium citrate (page 1033, third paragraph), therefore they teach buffered aqueous solution.

Regarding claim 20, Drake et al. teach extraction buffer containing ethanol (page 1033, fourth paragraph).

Regarding claim 21, Drake et al. teach mixing the extraction mixture by repeated pipetting (= agitating) (page 1033, fourth paragraph). Drake et al. do not specifically teach room temperature, but since the temperature is not specified, it was inherently room temperature.

Regarding claim 22, Drake et al. teach removal of the supernatant from the tube after centrifugation (page 1033, fourth paragraph), therefore they teach separation of the extraction mixture by decantation.

Regarding claim 23, Drake et al. teach separating the extraction mixture by centrifugation (page 1033, fourth paragraph).

Regarding claim 25, Drake et al. teach amplifying the extracted DNA by PCR (page 1033, last two paragraphs; page 1034, first paragraph; Fig. 2).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer et al. (J. AOAC Int., vol. 84, pp. 89-99, January 2001).

Meyer et al. teach centrifugation of the extraction mixture at 3,000 g and 10,000 g, but do not teach centrifugation of the extraction mixture at 15,000 g. However, it would have been prima facie obvious to perform routine optimization using reaction conditions, as noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable

ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific centrifugation conditions was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have optimized the conditions for extraction of DNA based on the disclosure of Meyer et al.

14. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Drake et al. (J. Food Protect., vol. 59, pp. 1031-1036, 1996), as evidenced by Meer (Food Colloids, Graham, H.D. editor, The AVI Publishing Company, Inc., Westport, Connecticut, pp. 522-539, 1977).

Drake et al. teach centrifugation of the extraction mixture at 7,500 g and 12,500 g, but do not teach centrifugation of the extraction mixture at 15,000 g. However, it would have been *prima facie* obvious to perform routine optimization using reaction conditions, as noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of specific centrifugation conditions was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have optimized the conditions for extraction of DNA based on the disclosure of Drake et al.

15. No references were found teaching or suggesting claim 26. Claim 26 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Teresa E Strzelecka
Teresa Strzelecka
Examiner
Art Unit 1637

February 14, 2005